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| 09/529,172      | 08/22/2000  | Meir Edelman         | EDELMAN=1           | 1629             |

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EXAMINER

MEHTA, ASHWIN D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1638     |              |

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14

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |               |                |
|------------------------------|---------------|----------------|
| <b>Office Action Summary</b> | Applicant No. | Applicant(s)   |
|                              | 09/529,172    | EDELMAN ET AL. |
|                              | Examiner      | Art Unit       |
|                              | Ashwin Mehta  | 1638           |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 February 2002.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-64 is/are pending in the application.

4a) Of the above claim(s) 19,37-53,59-61 and 64 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-18,20-36,54-58,62 and 63 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 & 11.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice to Comply with sequence rules.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-18, 25-36, and 54-58 in Paper No. 12, received 26 February 2002 is acknowledged. Applicants traverse the requirement at least to the extent that claims 20-24, 62, and 63 are directed to the same inventive concept as the claims of Group I. The traversal is on the ground(s) that claim 20 is directed to a method for the genetic transformation of a Lemnaceae plant, and claims 62 and 63 are dependent from claim 20, that claim 23 is directed to a method for the stable genetic transformation of a Lemnaceae plant, and claim 24 depends from claim 23 (response, page 1). Applicants' arguments were found persuasive and claims 20-24, 62, and 63 were rejoined with Group I. Claims 1-18, 20-36, 54-58, 62, and 63 are examined in this Office action.

The restriction requirement for claims 19, 37-53, 59-61, and 64 is still deemed proper and is therefore made FINAL. Non-elected claims 19, 37-53, 59-61, and 64 are withdrawn from consideration. The elected claims should also be amended such that they no longer encompass the non-elected inventions.

### ***Specification***

2. The specification fails to comply with the sequence rules of 37 CFR 1.821-1.825. The nucleotide sequences that appear on page 28, lines 7-8, need to be submitted as part of a sequence listing, in paper and computer-readable forms, and referred to in the specification by their assigned sequence identifiers. Please see the accompanying notice to comply.

***Drawings***

3. Information on how to effect drawing changes: **NOTE: THIS INFORMATION REPLACES THE INFORMATION THAT APPEARS ON THE BACK OF THE ACCOMPANYING FORM PTO-948.**

Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

***Claim Objections***

4. Claims 2-8, 13-18, 21, 22, 24, 26-35, 56, 57, 62, and 63 are objected to because of the following informalities:

The article “A” in line 1 of the claims should be --The--. Appropriate correction is required.

Further in claims 4 and 5: the claims are objected to under 37 CFR 1.75(c), because claim 4 is in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). The recitation “any one of” should appear in line 1 of claim 4 before “Claims”.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 9-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd. v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 4-7, 9-18, 20-23, 26-36, 54-58, 62, and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1: the recitation “and progeny thereof” renders the claim indefinite. It is not clear if the progeny contain nucleic acids that were transformed into the parent plant.

In claim 4: there is improper antecedent basis for the recitation “antibiotic resistant transformed Lemnaceae plant”.

In claim 6: there is improper antecedent basis for the recitation “herbicide resistant transformed Lemnaceae plant”.

In claim 7: the recitation “being tolerant to oxynil herbicides, to glyphosate and EPSPS inhibitor herbicides, to glufosinate or to HPPD inhibitors” renders the claim indefinite. Neither claim 7 nor the claims from which it depends indicates that the plant has been transformed with any herbicide resistant gene.

In claim 9-10: the claims provide for the use of the plant of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

In claim 12: the claim is indefinite because the final recited step is not consistent with the preamble. The claim is drawn towards a method for the stable genetic transformation of Lemnaceae plants. The claim recites that Lemnaceae plant and/or tissue is incubated with Agrobacterium. However, the last step only indicates that cells of the plant tissue, not the plant, are stably transformed.

In claims 14, 16, and 26: the claims are “Markush”-type claim that employs improper Markush terminology. In line 2 of the claims, “and” should be --or--.

In claims 20-23, 62 and 63: the claims are indefinite for being dependent upon a non-elected claim.

In claim 21: the recitation “an average diameter above about 150  $\mu\text{m}$ ” in lines 1-2 renders the claim indefinite. It is not clear if all of the particles share an average size, or if the particles can be any size that is above 150  $\mu\text{m}$ . It is also not clear what is encompassed by “above about.” The metes and bounds of the claim are not clear.

In claim 22: the recitation “an average diameter of about 150  $\mu\text{m}$  – 750  $\mu\text{m}$ ” renders the claim indefinite. It is not clear if the particles are in the range of about 150-750  $\mu\text{m}$ , or, if particles below 150  $\mu\text{m}$  and above 750  $\mu\text{m}$  are also encompassed, because of the term “average.” The metes and bounds of the claim are not clear.

In claims 27, 29, 34: the recitation “booster medium” renders the claims indefinite. It is not clear what the booster medium consists of. While the specification, for example at page 8, lines 1-17, explains generally what a booster medium can comprise, it is not clear what all examples of booster media are. For example, page 8, lines 2-4 indicates that a booster medium “may comprise” a fresh cell suspension of dicotyledonous plants. It is not clear what else is may comprise in place of this suspension. Page 8 also indicates the booster medium may alternatively comprise Lemnaceae plant extracts (lines 11-14). However, again, it is not clear what else the booster medium may comprise.

In claim 29: the claim recites the recitation “the booster medium” in line 1. There is insufficient antecedent basis for the limitation in the claim or the claims from which it depends.

In claim 30: the claim recites the limitation “the fresh cell suspension” in lines 1-2.

There is insufficient antecedent basis for this limitation in the claim.

In claim 32: the claim recites the recitation “the fresh cell suspension” in lines 1-2. There is insufficient antecedent basis for the limitation in the claim or the claims from which it depends.

In claim 33: the claim recites the recitation “the medium” in line 1. There is insufficient antecedent basis for the limitation in the claim or the claims from which it depends.

Further in claim 33: the recitation “medium caffeine” in line 3 renders the claim indefinite. It is not clear what is considered to be “medium” caffeine.

In claim 36: the claim is indefinite for being dependent upon a non-elected claim.

In claim 54: the recitation “coding said product” in line 2 renders the claim indefinite. It is not clear what is meant by this recitation.

Further in claim 63: the recitation “an average diameter of about 150  $\mu\text{m}$  - 750  $\mu\text{m}$ ” renders the claim indefinite. An average of a group of numbers, or in this case, size, is not referred to in terms of a range of sizes. It is suggested that the recitation be replaced with --a diameter of about 150  $\mu\text{m}$  to about 750  $\mu\text{m}$ --.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-8 and 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any genetically stable, transformed Lemnaceae plant and progeny thereof; or wherein said plant is of the genera Spirodela, Lemna, Wofflia, or being Spirodela punctata strain 8717; or any wherein said plant is antibiotic or herbicide resistant; or any transformed Lemnaceae plant produced by a method for the stable genetic transformation of Lemnaceae plant comprising incubating Lemnaceae plants and/or tissue with Agrobacterium cells.

The specification describes a method for the transformation of Lemna and Spirodela plants by microinjection with Agrobacterium. The bacterial cells were microinjected into meristematic zones (pages 13-17; 20-22). The specification describes the Agrobacterium-mediated transformation of Lemna and Spirodela particles and regeneration of plants therefrom. The particles were produced by blending, ranges in size from 350-750  $\mu\text{m}$ , and contained meristematic zones. Particles that were 150-350  $\mu\text{m}$  in size gave drastically reduced numbers of actively growing plants. Transgenic plants were recovered that contained a kanamycin resistance gene (pages 22-25). The specification also indicates that 5 different Agrobacterium strains were used in the transformation procedure, and that strains EHA105, EHA101, and GVE3103 only transformed meristematic tissue, whereas strains LBA4404 and C58 were restricted to transforming wounded areas of the mother frond (pages 25-26). The specification also indicates that vacuum infiltration of the Agrobacterium increased the transformation

efficiency (page 27). The specification also indicates that transformation efficiencies were increased by removing the daughter fronds and exposing the mother frond meristematic zones; co-cultivating Agrobacterium in a Spirodela extract prior to transformation (pages 28-29). Lemnaceae plants were also transformed with genes conferring resistance to the herbicide BASTA (pages 32-33).

However, the specification does not describe all stably transformed Lemnaceae plants and their progeny. The structures of all such transgenic plants, and their functions, are not described. While the specification describes Agrobacterium-mediated methods to transform Lemnaceae plants, the structures and functions of the plants themselves are not described. The structures of the transgenic Lemnaceae plants described in the specification as expressing GUS or comprising the nptII gene, the GFP coding sequence, and the bar gene for BASTA resistance are not representative of all the plants encompassed by the claims, which may comprise any type of transgene. The specification also does not describe all plants that comprise antibiotic or herbicide resistance genes, as such plants may also comprise any other type of transgene. The structures and functions of all such plants are not described. The specification also does not describe any plants that were transformed by non-Agrobacterium-mediated methods, which are also encompassed by the claims. The specification admits that plants could not be transformed by particle bombardment (page 3, lines 13-15). Given the breadth of the claims encompassing all genetically stable, transformed Lemnaceae plants produced by any means, and progeny thereof, and antibiotic and/or herbicide resistant Lemnaceae plants that can also comprise any other transgene(s) and having any function, and lack of guidance as discussed above, the

specification fails to provide an adequate written description of the multitude of transgenic plants encompassed by the claims.

8. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is directed to any genetically stable, transformed Lemnaceae plant wherein the plant is *Spirodela punctata* of strain 8717.

Since the claimed strain is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same strain and it is not apparent if it is readily available to the public.

If the strain is deposited under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein.

If the deposit will not be made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

***Claim Rejections - 35 USC § 102 & 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 2, 4-10, 12-16, 18, 20, 25, 26, 28, 36, and 54-57 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Stomp et al. (U.S. Patent No. 6,040,498), in light of Stachel et al. (Nature, 1985, Vol. 318, pages 624-629).

The claims are broadly drawn towards any genetically stable, transformed Lemnaceae plant and progeny thereof; or wherein the plant is of the genera Spirodela, Lemna, or Wolffia; any antibiotic or herbicide resistant transformed Lemnaceae plant; any Lemnaceae plant capable of expressing two or more foreign genes; a method for the stable genetic transformation of Lemnaceae plants comprising incubating Lemnaceae plants and/or tissue with Agrobacterium cells containing a transforming DNA molecule; or said method wherein the Agrobacterium cells are capable of targeting wounded regions in the plant, or wherein the Agrobacterium cells are from strains LBA4404 or C58; or said method wherein the plant's meristematic zone is exposed by removal of daughter fronds; or a method for the genetic transformation of Lemnaceae comprising cutting the plant into particles of a size such that they still contain undamaged meristematic tissue capable of developing into full plants, and incubating said particles with Agrobacterium; or a method of production of any product of interest, comprising growing said

transformed Lemnaceae plant under conditions enabling production of said product of interest, or wherein said product is purified, or wherein said product is any chemical or biological product.

Stomp et al. teach stably transformed duckweed plants including those from the genera Spirodela, Lemna, and Wolffia, and an Agrobacterium-mediated method for stably transforming duckweed tissue and regenerating a stably transformed plant therefrom. The plant tissue that is incubated with the Agrobacterium can preferably be made up of meristematic cells. The stably transformed plant comprises an antibiotic resistant gene, including that which confers resistance to kanamycin such as neo, and herbicide resistance genes such as EPSP. Transformation took place in a medium at pH 5.8, which can be considered to be about 5.2. Stably transformed plants can comprise heterologous nucleic acid comprising at least two genes of interest. Numerous Agrobacterium strains were used, including C58, EHA105 and EHA101 strains. Individual fronds were used in some transformation experiments, which indicates that daughter fronds would have to have been separated from mother fronds. It is inherent that such a separation would expose meristematic cells, as Stomp et al. teach that the meristematic cells lie on each side of the frond midvein, and that the stem that small midvein is the region where the stem arises that connects each frond to its mother frond. The transformation process further comprised cutting the individual fronds in meristematic regions. Agrobacterium target wounded cells, as taught by Stachel et al. (page 629). In light of this teaching, it is inherent that the Agrobacterium cells used by Stomp et al. are targeting wounded cells. Stomp et al. also teach a method of producing any recombinant proteins or peptides, comprising culturing a stably transformed duckweed plant under conditions that expresses the recombinant protein or peptides, and collecting the protein or peptides (claims; col. 1, lines 45-48; col. 33, line 15 to col. 61, line 30).

9. Claim 3 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stomp et al. (U.S. Patent No. 6,040,498).

The claim is broadly drawn towards any transformed *Spirodela punctata* plant of strain 8717.

Stomp et al. teach and claim transformed duckweed (Lemnaceae) plants, including those produced from any strain of the genus *Spirodela* (claims). The reference teaches all of the limitations of the claim but do not mention *Spirodela punctata* strain 8717. The examiner is unable to determine whether the prior art disclosure possesses the unrecited strain. However, the claim broadly encompasses transformed duckweed plants of any strain. The USPTO does not have sufficient facts to determine whether the transgenic duckweed plants taught by Stomp et al. encompass particularly strain 8717. The USPTO does not have sufficient facts to determine whether the instantly claimed duckweed plants and those of the reference are “inherently the same.” The USPTO cannot conclude that the subject matter of the instant claim would have been obvious since it cannot determine whether the transgenic plants taught and claimed by Stomp et al. encompass those that are strain 8717 or have the same properties as strain 8717 of the instantly claimed plants. The USPTO/examiner is not in a position to make either a conclusion of “inherency/anticipation” or “obviousness” since the record does not allow one to determine if and how the claimed subject matter differs from the prior art. Accordingly, the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the instantly claimed invention. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977).

10. Claim 11 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Welch et al. (Mol. Cell. Biol., 1985, Vol. 5, pages 1229-1237).

The claim is broadly drawn towards any chemical or biological product obtained by using a genetically stable transformed Lemnaceae plant for its production.

Welch et al. teach the purification of the 70-kilodalton heat shock proteins. The biological product taught by Welch et al. from the claimed chemical or biological product in its production. However, the process of making the claimed product does not distinguish it from those taught by the reference. See In re Thorpe, 227 USPQ 964,966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. Thus, the claimed invention was clearly prima facie obvious as a whole to one of ordinary skill in the art, if not anticipated by Welch et al.

11. Claims 1, 2, 4-10, 12-18, 20-30, 32, 34-36, 54-58, 62, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stomp et al. (U.S. Patent No. 6,040,498) in view of Stachel et al. (Nature, 1985, Vol. 318, pages 624-629), Vernade et al. (J. Bacteriol., 1988, Vol. 170, pages 5822-5829), Bechtold et al. (C.R. Acad. Sci. Paris, Sciences de la vie /Life Sciences, 1993, Vol. 316, pages 1194-1199), and Grimsley, N. (Agroinfection, In Methods in Molecular Biology, Vol. 44: Agrobacterium Protocols, 1995, K.M.A. Gartland and M.R. Davey, Eds, Humana Press Inc., Totowa, N.J.).

The claims are broadly drawn towards any genetically stable, transformed Lemnaceae plant and progeny thereof; or wherein the plant is of the genera Spirodela, Lemna, or Wolffia;

any antibiotic or herbicide resistant transformed Lemnaceae plant; any Lemnaceae plant capable of expressing two or more foreign genes; a method for the stable genetic transformation of Lemnaceae plants comprising incubating Lemnaceae plants and/or tissue with Agrobacterium cells containing a transforming DNA molecule; or said method wherein the Agrobacterium cells are capable of targeting wounded regions in the plant, or wherein the Agrobacterium cells are from strains LBA4404 or C58; or said method wherein the plant's meristematic zone is exposed by removal of daughter fronds or said method wherein during incubation with the Agrobacterium vacuum infiltration is applied; or said method wherein the Agrobacterium cells are brought into contact with any booster medium; or a method for the genetic transformation of Lemnaceae comprising cutting the plant into particles of a size such that they still contain undamaged meristematic tissue capable of developing into full plants, and incubating said particles with Agrobacterium; or said method wherein said particles have an average diameter of about 150  $\mu\text{m}$  or about 150-170  $\mu\text{m}$ ; or a method for the stable genetic transformation of Lemnaceae plants comprising microinjecting Agrobacterium cells into the meristematic zone of the plant, or wherein said method is carried out in planta; or a method of production of any product of interest, comprising growing said transformed Lemnaceae plant under conditions enabling production of said product of interest, or wherein said product is purified, or wherein said product is any chemical or biological product.

Stomp et al. teach an Agrobacterium-mediated method to produce stably genetically transformed Lemnaceae plants, and a method to produce any proteins or peptides comprising growing said transformed Lemnaceae plants, as discussed above. Stomp et al. also teach that

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vacuum pressure may be used during the infection step of the transformation method (col. 16, line 59 to col. 17, line 3).

Stomp et al. do not teach a vacuum infiltration method, microinjection with Agrobacterium, or a booster medium.

Stachel et al. teach that vir induction and the production of T-DNA circles during Agrobacterium transformation is mediated by acetosyringone and  $\alpha$ -hydroxy acetosyringone, which are produced by actively growing plant cells and are present in exudates of wounded plant cells, and that cultures tobacco root cells contain a vir-inducing activity and triggers the initiation of plant cell transformation (pages 624, 627-629).

Vernade et al. teach that optimal conditions for the efficient induction of Agrobacterium vir genes comprise a pH below 5.2 (pages 5823-5826).

Bechtold et al. teach an in planta method for Agrobacterium-mediated transformation of plants comprising vacuum infiltration (pages 1195-1198).

Grimsey teaches Agroinfection of plants, comprising injecting Agrobacterium cells into the meristematic region; uses of the process include the production of autonomously replicating viral vectors for the expression of large amounts of a gene product of interest, and insertion of viral sequences in the plant genome to confer virus resistance (pages 334-336).

It would have been obvious and within the scope of one of ordinary skill in the art at the time the invention was made to modify the Agrobacterium-mediated method for producing stably genetically transformed Lemnaceae plants of Stomp et al. by incubating the Agrobacterium with a medium of growing plants suspension cells, for example tobacco root cells, prior to or during the transformation step. One would have been motivated to incubate

Agrobacterium with such a medium, given the teaching of Stachel et al. that actively growing plant cells produce factors that induces vir and initiates transformation. The concentration of the cell suspension used amounts to a routine optimization of process parameters. It also would have been obvious to incubate the Agrobacterium with plant cell extracts, including extracts of *Spirodela punctata*, given the teaching of Stachel et al. that plant cell exudates also contain by acetosyringone and  $\alpha$ -hydroxy acetosyringone. It also would have been obvious to modify the method of Stomp et al. by adjusting the media in which the transformation takes place to 5.2 or below. One would have been motivated to make this adjustment, given the teaching of Vernade et al. that vir gene induction is optimal at pH below 5.2. The size of the cut Lemnaceae tissue used for transformation, including sizes of about 150-750  $\mu$ m, or larger, amount to a routine optimization of process parameters. It also would have been obvious to modify the transformation method taught by Stomp et al. by using vacuum infiltration to inoculate the target tissue with the Agrobacterium, for example by using the method of Bechtold et al. One would have been motivated to use vacuum infiltration given the teaching of Stomp et al. that vacuum pressure may be used during the infection step. It also would have been obvious to modify the method of Stomp et al. by microinjecting the Agrobacterium into the meristematic region, using method taught by Grimsley. One would have been motivated to use microinjection, as it provides a means to introduce an autonomously replicating viral vector to allow the expression of large amount of a product of interest, as taught by Grimsley.

11. No claim is allowed.

***Contact Information***

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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